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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,434	07/24/2003	Andrew Joseph Friedman	PRD-0007-US-CIP	9625

27777 7590 02/06/2008

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
02/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,434	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 12/6/2007. Claim(s) 6-8 have been cancelled. Claim(s) 1-5 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The double patenting and 103(a) rejection of the last Office Action are maintained for reasons of record and are repeated below for Applicant's convenience.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/385,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose an obvious variation of a method of contraception by administering to a menstruating female a composition

comprising estrogen and progestogen for 42 consecutive days followed by a hormone-free period.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/955,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose an obvious variation of a method of contraception by administering to a menstruating female a composition comprising ethinyl estradiol and norgestimate for 42 consecutive days followed by a hormone-free period. In both cases, the subtle differences in dosages and length of administration are obvious to one of ordinary skill in the art to optimize.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to address these grounds of rejection until allowable subject matter is disclosed is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being obvious over Kovacs et al. (The British Journal of Family Planning, 1994, 19, pg. 274-275) in view of Smallwood et al. ("Efficacy and Safety of a Transdermal Contraceptive System" Obstetrics & Gynecology, vol. 98, no. 5, part 1, 2001, pg. 799-805).

The instant claims are directed to a method of contraception comprising administering to a menstruating female a transdermal composition comprising ethinyl estradiol and norelgestromin for at least 56 successive days.

Kovacs et al. teach a trimonthly method of contraception (pg. 274, left column, paragraph 1) for menstruating women (pg. 275, right column, paragraph 9). The contraceptive comprises a daily dosage of ethinyl estradiol (estrogen) and a progestogen (levonorgestrel) (pg. 274, right column, paragraph 3) for 12 weeks followed by one week of placebo (pg. 274, left column, paragraph 1). Half of the female patients discontinued the regimen because of breakthrough bleeding (pg. 274, left column, paragraph 1).

However, Kovacs et al. does not specifically disclose the combination of ethinyl estradiol and norelgestromin.

Smallwood et al. teach a method of contraception comprising administering a daily transdermal composition comprising ethinyl estradiol (20 μg) and norelgestromin (150 μg) for 21 consecutive days followed by 1-week hormone-free period. This method provides enhanced bleeding control and is well tolerated (abstract). The women must be sexually active and at risk of pregnancy as well as have regular menstrual cycles (pg. 800, right column, second paragraph).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to substitute the contraceptive composition in the regimen as taught by Kovacs et al. with the composition comprising ethinyl estradiol and norelgestromin as taught by Smallwood et al.

A person of ordinary skill in the art would have been motivated to make this substitution because: (1) both Kovacs and Smallwood et al. teach a method of contraception by the administration of hormones; (2) both Kovacs and Smallwood et al. disclose the use of hormones, specifically ethinyl estrodiol (estrogen) in their regimen; and (3) because of the enhanced bleeding control and good tolerance in females in the regimen disclosed by Smallwood et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in providing a method of contraception in females by administering a transdermal composition comprising ethinyl estradiol and norelgestromin for at least 56 successive days.

Response to Arguments

Applicant argues that cited references do not teach a transdermal extended contraceptive regimen. This is not persuasive because clearly Kovacs et al. teach a

trimonthly method of contraception for 12 weeks and Smallwood et al. teach a method of contraception for 21 consecutive days using a transdermal composition.

Applicant argues that the cited references do not teach that extended transdermal contraceptive regimens provide enhanced continuation and satisfaction rates, longer median time-to-first bleed, fewer mean bleeding days through day 56, and reduced median incidence of headaches. Applicant also argues that these limitations are unexpected and surprising when compared to cyclic transdermal administration.

This is not persuasive because these limitations will be given little patentable weight. Firstly, the claims are drawn to a method of contraception and not to enhanced continuation and satisfaction rates, longer median time-to-first bleed, fewer mean bleeding days through day 56, and reduced median incidence of headaches. Secondly, these limitations are an inherent property or result when the same active agent is administered to the same patient population in the same dosage.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, these limitations are not considered unexpected or surprising because Smallwood et al. teach that the disclosed method of contraception provides enhanced bleeding control and is well tolerated.

Applicant continues to argue that the 103 rejection is improper because there is no motivation to administer ethinyl estradiol and norelgestromin for at least 42 consecutive days, particularly since Smallwood teach an administration for such combination for 21 consecutive days. The Kovacs reference teaching 84 consecutive days refers to only estrogen and progestin.

The rejection was formulated because it would have been obvious to substitute the active agents, ethinyl estradiol and progestogen (known hormonal contraceptives) in the contraceptive regimen of 84 consecutive days taught by Kovacs with the active agents, ethinyl estradiol and norelgestromin (known hormonal contraceptives), taught by Smallwood.

Half of the female patients in the Kovacs reference discontinued the regimen because of breakthrough bleeding. However, Smallwood teach enhanced bleeding control and good toleration from using a combination of ethinyl estradiol and norelgestromin.

Furthermore, both Kovacs and Smallwood teach a method of contraception by administering well-known hormonal contraceptives, of which the ethinyl estradiol (estrogen) is disclosed in both references. It is noted that progestogen (Kovacs) and norelgestromin (Smallwood) are functionally equivalent to each other since both are well-known to be progestins.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in substituting ethinyl estradiol and norelgestromin as taught by Smallwood in the contraceptive treatment regimen taught by Kovacs because: (1) both teach a method of contraception by administering hormones; (2) both teach administration of a combination of an estrogen and a progestin; (3) Kovacs teach that the 84 consecutive day treatment regimen suffers from breakthrough bleeding; (4) Smallwood teaches that the combination of ethinyl estradiol and norelgestromin provides enhanced bleeding control and good tolerance; and (5) because of the functional equivalence between norelgestromin and progestogen as progestins.

It is respectfully submitted that a recent Board Decision (Appeal 2007-3936 decided on 1/25/2008) on an analogous case (10/955,276) affirmed the Examiner for essentially the same reasons listed above while also citing KSR case law.

Briefly, the obviousness rejection was formulated because it would have been obvious to substitute the active agents, ethinyl estradiol and progestogen, in the contraceptive regimen of 84 consecutive days taught by Kovacs with the active agents, ethinyl estradiol and norgestimate, taught by Shangold.

The Board makes that point that a combination of the two contraceptive regimens has elements that advantageously solve known problems (pg. 12, second paragraph).

This is supported by KSR case law, which states that it is obvious to apply known solutions to a problem recognized in the prior art if there are a finite number of identified, predictable solutions. A person of ordinary skill has good reason to pursue

known options within his or her technical grasp. If this lead to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (pg. 10).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHEENI PADMANABHAN
SUPERVISORY PATENT EXAMINER